IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

Health Choice Group, LLC and Jaime Green, on behalf of The United States of America, et al, Plaintiffs/Relators, v. Bayer Corporation, et al, Defendants.	Civil Action No. 5:17-cv-126-RWS-CMC

DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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STATEMENT OF THE ISSUES

1. Whether Relators have failed to state a claim on which relief may be granted under the False Claims Act ("FCA") and similar state laws due to their failure to plead the requisite elements of falsity, scienter, and causation.
2. Whether Relators have failed to meet the heightened pleading requirements of Rule 9(b) for all counts.
3. Whether a substantial portion of Relators' claims are barred by statutes of limitations.
4. Whether the First Amended Complaint ("FAC") improperly attempts to add a new Relator.

STATEMENT OF THE CASE

Defendants Bayer Corporation ("Bayer), Amgen, Inc. ("Amgen"), Onyx Pharmaceuticals, Inc. ("Onyx"), AmerisourceBergen Corporation ("Amerisource"), and Lash Group ("Lash") (collectively "Defendants") respectfully move to dismiss Relators' FAC.

Relators assert claims under the FCA and similar state laws. Only the private party *qui tam* relators are pursuing this case; the federal and state governments (collectively, the "Government") declined to intervene. Relators allege that each Defendant caused the submission of false claims for reimbursement of prescription drugs to government healthcare programs. Those claims were false, Relators allege, because product support and education programs that Defendants operated for those drugs—nurse educator and insurance reimbursement assistance programs—violated the Anti-Kickback Statute ("AKS") and similar state laws. The FAC should be dismissed under Rule 12(b)(6).

First, the FAC fails to establish any "false" claim because it fails to allege facts to plausibly show that Defendants violated the AKS. Two of Relators' theories (nurse educator programs and reimbursement support services) do not state a kickback violation because they explicitly allege that only product-specific support was provided for the three medicines at issue.

Guidance materials from the Office of the Inspector General ("OIG") of the U.S. Department of Health and Human Services have made clear that such product-specific support services that do not provide substantial independent value to doctors are not illegal remuneration under the AKS.

Relators' other theory (*i.e.*, broad, conclusory allegations of "white coat marketing" through nurse educators) also fails to state an AKS violation. The specific facts alleged show that the AKS is not implicated because those nurses merely educated doctors and patients about the medicines, rather than "recommending" the medicines because of any alleged remuneration. Moreover, this theory also fails because it relies on a faulty legal premise that all promotional activities by non-employee health care providers necessarily violate the AKS.

Second, even if Relators had alleged Defendants violated the AKS and thereby created "false" claims, the FAC falls well short of alleging that the Defendants *knowingly* did so. Well established Fifth Circuit case law requires that a defendant actually knew that the claim was false before FCA liability can attach. The FAC fails to allege plausible facts that Defendants knew their actions violated the AKS and thereby created false claims. Indeed, in light of the OIG guidance documents and other regulations permitting the conduct Relators allege (including product-specific support services and education through nurse educators), Relators cannot as a matter of law demonstrate that Defendants knew their actions would create false claims because those actions were objectively reasonable.

Third, Relators have not alleged facts to show Defendants' actions caused the submission of a false claim to a government healthcare program. At most, Relators claim the alleged acts occurred over a period of several years and speculate that the acts must have caused the submission of a claim to a government healthcare program during that time. Such conjecture is inadequate.

Furthermore, Relators fail to plead their claims of fraud with particularity as required by Fed. R. Civ. P. 9(b). The heightened standard of Rule 9(b) requires the "who, what, when, where, and how" of the alleged acts. Those facts are missing from the FAC. For example, despite the FAC's acknowledgement that Amgen and Onyx were involved only in one of the medicines at issue—Nexavar—the FAC repeatedly makes undifferentiated allegations about all Defendants with respect to all three medicines at issue. The FAC similarly fails to explain which Defendant undertook what alleged act, when those acts occurred and with whom, and—of particular importance—how those alleged acts caused a false claim that was submitted to the Government. In short, Relators have failed to allege with particularity that any false claims were submitted, or to link any such false claims to the alleged kickback schemes. Relators cannot proceed without such particularized allegations.

Finally, the FAC asserts claims beyond the statute of limitations period and improperly attempts to add a new plaintiff relator (Jaime Green) in violation of the FCA's first-to-file rule.

BACKGROUND

This *qui tam* case was filed under seal on June 19, 2017. Dkt. 1. After only four months, the Federal Government and all State Governments declined to intervene and the complaint was unsealed on October 31, 2017. Dkt. 7, United States' Notice of Election to Decline Intervention; Dkt. 8, Order Unsealing Complaint. The FAC was filed on January 12, 2018. Dkt. 32. The original relator is Health Choice Group, LLC ("Health Choice"), "an affiliate" of a non-party "research organization" called National Healthcare Analysis Group. FAC ¶ 26.

Relator Jaime Green ("Green") was added in the FAC. Green is a nurse formerly employed by non-party Ashfield Healthcare LLC ("Ashfield") as a nurse educator regarding the Bayer drug product Adempas, a product first added to this case by the FAC. *Id*. at ¶ 27. Green

does not identify any FAC claims or allegations as being hers alone, but instead shares with Health Choice all of the claims and allegations in the FAC. *Id*. at 1.

Defendants Bayer, Amgen, and Onyx are pharmaceutical or biopharmaceutical companies. *Id*. at ¶¶ 21-23. There are three prescription drug products at issue in the FAC. Two are Bayer products: Betaseron (used to treat multiple sclerosis) and Adempas (used to treat pulmonary hypertension). *Id*. at ¶ 2. The third medicine, Nexavar (used to treat cancer), has been co-marketed by Bayer, Amgen, and Onyx. *Id*. Collectively, Betaseron, Nexavar, and Adempas are hereinafter collectively referred to as "the Medicines." Defendants allege that Amerisource and Lash, and non-party Ashfield, carried out certain drug product support programs (described below) that are the focus of the FAC.

A. The Nature of the FAC's Claims

The FAC purports to assert claims for violations of the FCA and similar state laws. *Id*. at ¶¶ 205-375. In brief, the FAC alleges that Defendants caused false claims for reimbursement for purchases of the Medicines to be submitted to Government healthcare programs. *Id*. at ¶ 17. Those claims were false, the FAC alleges, because they were tainted by violations of the AKS. *Id*. at ¶ 85. The sole harm alleged is that the Government would not have paid to reimburse for some unidentified prescriptions had the Government been aware of Defendants' allegedly unlawful drug product support programs. *Id*. at ¶¶ 15-17.

The FAC does *not* allege: (1) any harm to patients; (2) any inappropriate use of the Medicines; (3) any unapproved uses of those Medicines; (4) that particular prescribers would not have prescribed those Medicines but for the Defendants' allegedly unlawful actions; or (5) that Government healthcare programs did not get exactly what they paid for.

B. The Drug Product Support Programs at Issue

The FAC challenges the legality of two types of drug product support programs that one or more of the Defendants allegedly provided for one or more Medicines.

First are the nurse educator programs, under which trained nurses educate patients about the nature and proper use of the specific drug product that was prescribed by a doctor. *Id*. at ¶¶ 92-107. The nurse educators provide patients with information on such matters as the relevant disease state and proper administration of the specific drug prescribed. *Id*. at ¶ 97. They also similarly educate doctors and their staff on these topics. *Id*. at ¶ 102. Each nurse educator program provides these services for only one of the Medicines. *Id*. at ¶ 95. Relators allege that the nurse educators are employed directly or indirectly by either Amerisource, Lash, or Ashfield, pursuant to those entities' contracts with one or more of the biopharmaceutical companies Bayer, Amgen, and Onyx. *Id*. at ¶¶ 92, 107.

Second are the insurance reimbursement assistance programs, where skilled workers assist in obtaining insurance coverage for purchases of one of more of the Medicines. *Id*. at ¶¶ 146-73. These services include assisting with patient insurance benefit verification, patient prior authorization, and coverage appeals. *Id*. at ¶¶ 148, 159-62. These reimbursement support services are provided by Bayer and Amgen with assistance from Lash. *Id*. at ¶ 91.

C. The FAC's Theories of AKS Violations.

The FAC alleges three separate theories of AKS violations. The first and third theories contend that the services provided by both support programs – reimbursement assistance and nurse educator programs – are illegal remuneration to doctors provided to induce *doctors* to prescribe or recommend the Medicines. *Id*. at ¶¶ 89, 91-107; 146-73. The second theory (as plead in the FAC) contends that the salaries paid to nurse educators are illegal remuneration to induce those *nurses* to recommend the Medicines. *Id*. at ¶¶ 90, 108-45.

1. The Two Theories of Remuneration to Doctors (Theories One and Three)

The FAC alleges that the services provided by the nurse educator program ("Theory One" or "the 1st Theory"), and those provided by the reimbursement assistance program ("Theory Three" or "the 3rd Theory"), reduced the operating expenses of doctors who otherwise may have borne the expense of providing such services to their patients and/or the doctors' staff. *Id*. at ¶¶ 89, 91. Relators contend that those services constituted illegal AKS "remuneration" unlawfully intended to induce doctors to prescribe the Medicines. *Id*. at ¶ 91. The FAC devotes several pages to discussing the law and OIG guidance that allegedly demonstrate that these services are unlawful remuneration to doctors in violation of the AKS. *See, e.g.*, *id*. at ¶¶ 7, 107.

The FAC does not, however, mention any of the OIG guidance specific to the types of product support programs at issue here. As explained below, that omitted OIG guidance provides that product support programs such as these are not unlawful remuneration to the doctors because those services are provided solely in connection with the Medicines and do not provide substantial independent value to doctors. The FAC expressly states that the alleged product support programs are only for the Medicines. *Id*. at ¶¶ 95, 147.

2. The Theory of Remuneration to Nurses (Theory Two)

The FAC also purports to allege that the salaries paid to nurse educators are unlawful remuneration to induce those nurses to recommend the Medicines. *Id*. at ¶ 111. The FAC alleges generally that the nurse educators did not merely "educate" others about the products at issue, but also affirmatively "recommended" those products to patients, doctors, and their staff, which the FAC calls "white coat marketing." *Id*. at ¶¶ 140, 145. The FAC asserts a legal conclusion that the AKS prohibits Defendants "from paying non-employees to 'recommend'" the Medicines to others. *Id*. at ¶ 114.

However, the conclusory allegation that the nurse educators "recommended" the products at issue is expressly identified in the FAC itself as being merely an inference or "conclusion" that the FAC argues should be drawn from other specifically identified fact allegations. *Id*. at ¶ 116. None of those fact allegations, however, support a reasonable inference that the nurse educators recommended the Medicines. *Id*. at ¶¶ 117-45. Instead, they indicate that the nurse educators supported the Medicines by merely educating patients, doctors, and their staff about the nature and proper use of those products. *Id*.

STANDARD

Rule 12(b)(6) requires Relators to state a plausible claim for relief by making sufficient factual allegations such that the court may reasonably infer "that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This requirement extends to "each element" necessary to sustain recovery under some actionable legal theory. *Pena v. City of Rio Grande City*, 879 F.3d 613, 621 (5th Cir. 2018). The purpose of this requirement is that if "the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 558).

"Claims brought under the FCA are fraud claims that must also comply with the supplemental pleading requirements of Rule 9(b), demanding that 'a party must state with particularity the circumstances constituting fraud or mistake.'" *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 892 (5th Cir. 2013) (quoting Fed. R. Civ. P. 9(b)). That requires that Relators explain "the who, what, when, where, and how" of the alleged fraud. *Benchmark Electronics, Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003).

ARGUMENT

I. Counts 1 and 2 Should Be Dismissed Pursuant to Rule 12(b)(6) Because the FAC Fails to Plead the Essential Elements of Falsity, Scienter, and Causation.

Counts 1 and 2 are brought under 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B), respectively. Under Section 3729(a)(1)(A), Relators must allege that: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (*i.e.*, that involved a claim)." *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 259 (5th Cir. 2014) (quotations and citations omitted). Section 3729(a)(1)(B) creates liability for one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." An underlying false claim is an element of both sections. *U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 476–77 (5th Cir. 2015), *aff'd* 137 S. Ct. 436 (2016) ("To prove a violation of both § 3729(a)(1) and § 3729(a)(1)(B), the [relators] had to show that the claim presented for payment . . . was false."). Relators do not, and cannot, satisfy the elements of falsity, scienter, or causation, so Counts 1 and 2 should be dismissed with prejudice.

A. Relators' Allegations Do Not and Cannot Establish Falsity Because They Do Not Plausibly Allege Any Violation of the AKS.

An actual "false claim" is the *sine qua non* of FCA liability. *U.S. ex rel. Foster v. Bristol-Meyers Squibb Co.*, 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008). Relators seek to establish the falsity element based entirely on the allegation that each Defendant violated the AKS by offering remuneration to induce doctors to prescribe (Theories One and Three) and to induce nurses to recommend (Theory Two) prescription drugs for which claims for reimbursement were submitted to federal and state health care programs. FAC ¶¶ 89-91.

Relators allege that by violating the AKS, Defendants caused all claims connected to that violation to become "false." *Id*. at ¶¶ 16-17, 188.

The elements of an AKS violation under 42 U.S.C. § 1320a-7b(b)(2) that Relators must plead are that Defendants: (1) offered or paid remuneration to others; (2) to induce them to purchase, order, or recommend purchasing any good or item that may be paid by a federal health care program, and (3) did so knowingly and willfully. *See United States v. Shoemaker*, 746 F.3d 614, 627 (5th Cir. 2014). Under a plain reading of the AKS and relevant case law, Relators do not, and cannot, meet their burden of pleading an AKS violation and therefore have not pled falsity. Relators must plead their FCA claim with particularity, including *each element* of the alleged AKS violations. *See United States v. Paramedics Plus LLC*, No. 4:14-CV-00203, 2017 WL 4812443, at *4 (E.D. Tex. Oct. 25, 2017) ("In such a case, the elements of the AKS violation must also be pleaded with particularity under Rule 9(b), because they are brought as a FCA claim.").

1. *The Alleged Nurse Education Programs (Theory One) and Reimbursement Support Services (Theory Three) Do Not Provide Unlawful Remuneration To Doctors in Violation of the AKS.*

Relators' central premise that nurse education and reimbursement support services described in Theories One and Three provide illegal remuneration under the AKS is incorrect as a matter of law because each of the services described are limited to the support of one of the Medicines and provide no substantial, independent value to prescribers. *See* FAC ¶ 95 (describing medicine-specific programs for Betaseron, Nexavar, and Adempas), *and* ¶ 146 (alleging "reimbursement support services for Prescribers who wrote prescriptions for Betaseron or Nexavar"). The OIG issued guidance in 2003 regarding whether support services can trigger AKS liability, noting that "support services . . . tied to support of the purchased product" do not constitute illegal remuneration under the AKS without some additional showing of other

"substantial independent value to the purchaser." OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("Compliance Program Guidance"), 68 FR 23731-01, 2003 WL 2010428, at *23735. OIG has similarly explained that services with no independent value "apart from the products" do not run afoul of the AKS. *See, e.g.*, OIG Adv. Op. 00-10, 2000 WL 35747420, at *4 ("Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, . . . these services have no substantial independent value and do not implicate the [AKS].").

Courts addressing this issue agree with the OIG's interpretation. *See U.S. ex rel. Forney v. Medtronic, Inc.*, No. CV 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017). Relators' education and reimbursement support allegations are virtually identical to those made and dismissed in *Medtronic*. *Id. at* *4. Specifically, the *Medtronic* relator challenged "free assistance on billing [Medtronic's] devices to federal health care programs", *id.* at *2, just as Relators here challenge Defendants providing "reimbursement support services" to doctors who prescribed the Medicines. FAC ¶ 91. The *Medtronic* relator, just as Relators here, similarly claimed the services constituted "free labor" provided by the manufacturer in order to induce physicians to use Medtronic products. *Compare* 2017 WL 2653568 at *4, *with* FAC ¶¶ 89, 91.

In granting Medtronic's motion to dismiss, the court stated that "product support services that are 'specifically tied to support of the purchased product' standing alone do not implicate the AKS":

> [S]uch product support services are permissible unless they are not tied to the product purchased, or if they provide some *substantial independent value* to the purchaser. . . . Offering well-supported products might induce physicians to

> purchase Medtronic products, but only because they are better-supported products than competing products.

Medtronic, 2017 WL 2653568 at *4 (citing OIG Compliance Guidance at 19-20) (emphasis added); *see also* OIG Adv. Op. 12-20, 2012 WL 7148096, at 1-3 (concluding that situation in which a hospital provided physicians "free access" to an "Interface to transmit to the [hospital] orders for laboratory . . . services to be performed by the [hospital] . . . would not generate prohibited remuneration under the anti-kickback statute" because the Interface and related support services were "integrally related to the Requestor's services, such that the free access would have no independent value to the Physicians apart from the services the Requestor provides").

Here, Relators' *own allegations in the FAC* satisfy the OIG test and foreclose their claims premised on nurse educator programs and reimbursement services. The FAC alleges that the services are tied to the products purchased. *See, e.g.*, FAC ¶¶ 95, 97, 150. Relators' express acknowledgement that the alleged services were limited to the specific products is fatal to any claim that the subject activities constitute unlawful remuneration to doctors under the AKS.

As the OIG has implied, services that are integrally related to only the products purchased do not provide "substantial independent value" because they lack broader application in the doctor's practice. But even if such services could theoretically provide value independent from the purchased product, the services described in the FAC do not. As in *Medtronic*, Relators here speculate that the services "reduced the time and cost" of treating patients, provide "tangible benefits," "freed up time to see other patients", and "increased profitability." *Id*. at ¶¶ 102, 104, 106-07, 147, 151, 163. These allegations do not plausibly demonstrate the "substantial independent value" to doctors' offices that is needed for an AKS violation. At most, Relators' allegations, if true, would show only that the Defendants "offer[ed] well-supported products,"

Cf. Medtronic, 2017 WL 2653568, at *4, but fail to plead a violation of the AKS violation and, therefore, "falsity" under the FCA.[1]

2. Relators Fail to Allege Plausible Facts That Unlawful Remuneration Was Paid to Nurse Educators to Induce Them to Recommend the Medicines (Theory Two).

Relators do not allege that Defendants' payments to nurse educators for merely educating doctors and patients about the Medicines violate the AKS. Relators' second theory, instead, alleges a violation of the AKS based upon salary payments to nurse educators for the provision of educational services by merely labeling these services as efforts to "recommend" the Medicines based upon inferences Relators argue should be drawn from the FAC's factual allegations. But even if this legal theory were sound—which, for the reasons discussed below, it is not—it is not supported by the FAC's fact allegations. Relators' assertion that the nurses recommended those products is based entirely on a mere inference that Relators argue should be drawn from other identified fact allegations. Those other fact allegations plainly do not reasonably support any such inference. The FAC thus fails the *Twombly/Iqbal* requirement to plausibly allege this AKS violation theory.

The FAC concedes that its allegation that the nurse educators recommended the products at issue is merely an inference, or "conclusion," that Relators argue "is compelled by numerous facts" alleged in the FAC. FAC ¶ 116. But none of those "numerous facts" reasonably support that inference. Indeed, the fact allegation that Relators rely on most heavily for this inference—an allegation that the nurse educators were not permitted to talk to doctors or patients about

[1] Moreover, any allegations of "substantial independent value" fail for the additional reason that they are not pled with the particularity required by Rule 9(b). Relators have pled no details to demonstrate how the alleged nurse education and support services actually provided any financial benefit for the doctors. "Simply stating that services generally benefited [prescribers'] bottom lines or that physicians used [the] services 'in lieu of having to pay for their own employees' is not sufficiently specific to meet the pleading requirements of Rule 9(b) . . . ." *Medtronic*, 2017 WL 2653568 at *4.

products other than those at issue—is more consistent with the nurse educators limiting their roles to educating others about only the Medicines, as opposed to affirmatively recommending those products to doctors or patients. *Id*. at ¶¶ 131-39.

The other "numerous facts" on which the FAC relies to support Relators' conclusion that nurse educators recommended the Medicines fare no better. All are entirely consistent with merely educating about those products, as opposed to recommending them. *Id*. at ¶¶ 117-20 (nurses were trained in how to interact with prescribers; no training to "recommend" the Medicines); *id*. at ¶¶ 121-24 (nurses coordinated with sales reps on visits to doctors; no mention of nurses recommending products to doctors); *id*. at ¶¶ 125-30 (nurses gained access to doctors; no mention of recommending products to doctors); *id*. at ¶¶ 140-44 (nurses were "educating patients"; no mention of recommending products to patients).

The alleged statements by the nurse educators upon whose alleged "confidential interviews" the FAC is expressly based are inconsistent with any inference that the nurses were recommending products, as opposed to providing education services. The FAC quotes from hand-selected excerpts of the alleged interviews, but none of those statements even suggests that the nurses went beyond educating and into recommending any products. *Id*. at ¶ 125 (discussing arranging meetings with doctors; no mention of recommending any product); *id*. at ¶ 135 (discussing communicating with doctors about patients; no mention of recommending any product); *id*. at ¶ 138 (discussing "educating" other nurses; no mention of recommending any product); *id*. at ¶ 142 (discussing "educating patients"; no mention of recommending any product).

The gist of Relators' theory that the nurse educators recommended the Medicines is that the nurse educators' access to doctors and nurses put them "in a prime position to recommend"

those Medicines and to thus further the Defendants' sales objectives. *Id*. at ¶ 140. But alleging mere "opportunity and motive" does not reasonably support an inference of action. *See, e.g.*, *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level."); *see also Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1205–06 (11th Cir. 2007) ("Our duty to accept the facts in the complaint as true does not require us to ignore specific factual details of the pleading in favor of general or conclusory allegations.").

Moreover, Relators' legal premise—that "the AKS prohibits pharmaceutical companies from paying non-employees to 'recommend' its drugs to others," FAC ¶ 114—is simply wrong. The AKS has both statutory and regulatory "safe harbors" expressly permitting pharmaceutical companies to engage non-employees to provide services. *See* 42 U.S.C. § 1320a-7b(b)(3)(C); 42 C.F.R. § 1001.952(d) (listing relevant factors in evaluating "personal services and management contracts" for non-employee agents, including those engaged in promotion). And in direct contrast to Relators' legal conclusion, the OIG's Compliance Program Guidance makes crystal clear that merely paying a third-party contractor to "recommend" a product, without more, is not a violation of the AKS. *See* 68 FR 23731-01, at 23739 ("Sales agents, whether employees *or independent contractors*, are paid *to recommend* . . . the items they offer for sale on behalf of the pharmaceutical manufacturer they represent. *Many arrangements can be structured to fit in the* employment or *personal services safe harbor*.") (emphasis added).

Relators have, at most, alleged that Defendants paid nurse educators to educate others about the Medicines. This is not an AKS violation.

B. Relators Have Failed to Allege Facts That Establish the Requisite Scienter.

Relators fail to plead sufficient facts to demonstrate the necessary FCA element that each defendant "knowingly" caused the submission of false claims. *See Bollinger Shipyards*, 775 F.3d at 259. "Knowingly" is defined in the FCA to "mean that a person, with respect to

information—(i) has actual knowledge of the information, (ii) acts in deliberate ignorance of the truth or falsity of the information, or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(A). An incorrect interpretation of "vague provisions or regulations" does not create a "knowingly" false claim. *See United States v. Southland Mgmt. Corp*., 326 F.3d 669, 682 (5th Cir. 2003) (en banc) (Jones, J., concurring); *see also U.S. ex rel. Johnson v. Kaner Med. Grp, P.A*., 641 F. App'x 391, 394 (5th Cir. 2016) (noting "knowingly" is "an elevated standard" requiring more than "negligence or gross negligence"). Only a "lie is actionable" under the FCA, "not an error." *Id*.

As explained above, Relators' theory that the claims at issue were "false" is based entirely on the allegation that Defendants violated the AKS. To plead a violation of the FCA under this theory, relators must therefore plausibly allege that Defendants knew their acts, as knowledge is defined in the FCA, violated the AKS and therefore "knowingly" caused others to submit a false claim. Relators have failed to meet this standard. *See U.S. ex rel. Jamison v. McKesson Corp.*, No. 2:08-CV-214, 2012 WL 487998, at *4 (N.D. Miss. Feb. 14, 2012) ("[A] claim is legally false when the claimant *knowingly falsely certifies* that it has *complied with a statute* or regulation the compliance with which is a condition for Government payment.") (emphasis added).

A defendant cannot "knowingly" cause another to submit a false claim on the basis of an underlying legal violation where the defendant's conduct complied with an objectively reasonable interpretation of the law. *See U.S. ex rel. Purcess v. MWI Corp.*, 807 F.3d 281, 288–89 (D.C. Cir. 2015). The Supreme Court has held that "[w]here . . . the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation

as a knowing or [willful] violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007); *see also U.S. ex rel. K & R L.P. v. Mass. Hous. Fin. Agency,* 530 F.3d 980, 983 (D.C. Cir. 2008) (applying *Safeco* to affirm summary judgment for defendant in FCA case); *U.S. ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 932 (S.D. Tex. 2007) ("Claims are not 'false' under the FCA when reasonable persons can disagree regarding whether service was properly billed to the Government."), *aff'd sub nom. U.S. ex rel. Gudur v. Deloitte & Touche*, No. 07-20414, 2008 WL 3244000 (5th Cir. Aug. 7, 2008). Moreover, Relators' FCA claims are based on alleged violations of the AKS, which additionally requires that the Defendants act "willfully," *i.e.*, "with the specific intent to do something the law forbids." *United States v. Gibson*, 875 F.3d 179, 188 (5th Cir. 2017) (quotation and citation omitted); *see also United States v. Njoku*, 737 F.3d 55, 64 (5th Cir. 2013) (same).

Relators have failed to plead any facts demonstrating that Defendants actually *knew* that their product-specific support services violated the AKS or were otherwise unlawful. Instead, Defendants' product support services complied with an objectively reasonable interpretation of the AKS case law and relevant OIG guidance documents.

Theories One and Three: As an initial matter, Relators fail to even allege that Defendants knew the programs at issue violated the AKS. Without such allegations, Relators fail to plead that Defendants knowingly caused the submission of a false claim. However, even if Relators had made this allegation, as explained in Section I.A.1, Relators cannot establish knowledge under the FCA because their allegations do not, as a matter of law, establish a violation of the AKS under the reasoning set forth in the OIG Compliance Program Guidance and *Medtronic*. At the very least, the OIG Compliance Program Guidance shows that it is not clear that these programs violate the AKS, which prevents any finding of a knowing FCA violation. *See Gudur*,

512 F. Supp. 2d at 932. As a result, Relators have not and cannot establish the necessary scienter for these claims and all claims under these theories should be dismissed with prejudice.

Theory Two: Relators have not sufficiently pled that Defendants paid nurse educators to recommend the Medicines. But even assuming they had done so, Relators cannot establish that "promotional" activity by the nurse educators necessarily would violate the AKS and therefore that Defendants *knew* those acts violated the AKS. As explained above, *supra* Section I.A.2, statutory and regulatory "safe harbors" allow pharmaceutical companies to utilize non-employees in promotional activities. And the OIG Opinion that Relators rely on states only that the use of "a physician or other health care professional . . . involved in [marketing] activity" is "closely scrutinized." OIG Adv. Op. 11-08, 2011 WL 4526111, at *4. It does not state such activity is categorically prohibited. By not prohibiting health care professionals from engaging in all situations of marketing activity, the OIG Guidance makes it, at the very least, ambiguous whether these programs violate the AKS. This ambiguity allows for more than one reasonable interpretation of the law and, even assuming Relators' allegations as true, prohibits as a matter of law any finding that Defendants knowingly violated the FCA under Theory Two. *See Gudur*, 512 F. Supp. 2d at 932.

Additionally, the specific facts alleged in the FAC contradict any "knowing" violation under Theory Two. The nurse educators quoted explained that they understood they "were there to help educate," not recommend. FAC ¶ 136. The educators were trained on the Medicines and instructed to not "talk about competitor drugs." *Id*. at ¶¶ 118, 132. The facts alleged show that Defendants took measures to ensure the purpose of each nurse was to educate about the Medicines, not to recommend it over competing products. In short, Relators have alleged no facts to show a nurse educator did more than educate, and they certainly have failed to establish

that Defendants knew the nurse educators did so. These allegations from the FAC negate any plausible inference that the Defendants knowingly caused the submission of false claims.

C. Relators Have Failed to Allege Facts to Establish Causation.

To state an AKS-based FCA claim, Relators also must allege facts to show the Defendants' challenged actions "actually caused . . . physicians to prescribe" the Medicines and that those prescriptions were then reimbursed by the Government. *See U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("[I]t would be speculation to infer that compensation for professional services legally rendered *actually caused* the physicians to prescribe [defendant's] drugs to Medicaid patients.") (emphasis added). The relator must "sufficiently link" the payment of remuneration "to a referral, patient, or claim." *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *24 (N.D. Tex. June 20, 2016), *reconsideration denied sub nom. U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-0604-M, 2017 WL 5483747 (N.D. Tex. Nov. 14, 2017). Mere temporal proximity of the remuneration to the claims, or statistical probability, is not enough. *Id*. at *25 ("The mere fact that 93% of Defendants' patients are Medicare patients is not sufficient to show Defendants submitted claims that falsely certified compliance with the AKS.").

As an initial matter, Relators' own allegations suggest the prescription of the Medicines was caused by factors other than any alleged remuneration. The confidential interviewees from Relator Health Choice Group's investigation admit that the Medicines are "beneficial" and the data "clearly show[s]" that the Medicines are superior to competing drugs. *See* FAC ¶¶ 137, 143. As such, without additional facts that are not found in the FAC, causation is speculative.

Theories One and Three: Relators offer conclusory allegations regarding the process for the submission of claims to Medicare, Medicaid, VA, and Tricare, *id*. at ¶¶ 41-86, but they fail to demonstrate the necessary causal link between the submission of these claims and Theories One

and Three. They do not allege any specific instance in which one of the Medicines was prescribed or a claim was submitted *as a result of* either the nurse educator programs or the reimbursement support services. Nor do they then make the necessary connection that any such claim was then submitted through the Medicare, Medicaid, VA, or Tricare programs to the Government. Moreover, there are no allegations under which the remuneration alleged was conditioned on doctors prescribing Medicines to patients who would then be reimbursed from the Government. *See King*, 871 F.3d at 332 ("There was nothing illegal about paying physicians for their participation in these types of programs and there is no evidence that participation was conditioned upon prescribing [defendant's] drugs to Medicaid patients.").

In short, Relators' allegations are inadequate, and as courts have held, it is not enough for Relators to "portray[] the scheme and then summarily conclude[]" that false claims were submitted. *See U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 782 (S.D. Tex. 2010); *see also U.S. ex rel. Kroening v. Forest Pharmaceuticals, Inc.*, 155 F. Supp. 3d 883, 893-94 (E.D. Wisc. 2016) (granting motion to dismiss FCA claims where relator could provide only "scant details" linking scheme to government-reimbursed prescriptions).

Theory Two: Relators similarly fail to establish a causal link between the submission of false claims and the conduct alleged in Theory Two. Despite conclusory statements about "white coat marketing," Relators do not make the needed connection that false claims resulted from these practices. *U.S. ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 372 (5th Cir. 2017) (granting motion to dismiss where "[n]o particulars [were] alleged to show" causation and where "complaint never link[ed] the alleged carrots [*i.e.*, remuneration] to the purchase and use of the stents at either of the hospitals.").

Relators concentrate on repeating that "nurse educators gained access to Prescribers," *see* FAC ¶¶ 125-26, 128, 130, but they do not explain how this access—or any of the alleged actions of nurse educators in the course of this alleged "access"—resulted in false claims that were then submitted to the Government. Without the details of the needed causal link, causation under Theory Two is based on speculation alone, which is not enough. *See King*, 871 F.3d at 332.

II. All of Relators' FCA Claims (Counts 1-3) Should Be Dismissed Pursuant to Rule 9(b) Because Relators Have Not Pled Fraud With Particularity.

Where, as here, a relator bases an FCA claim on a violation of the AKS, the elements of both must be pled with the particularity required by Fed. R. Civ. P. 9(b). *Paramedics Plus LLC*, 2017 WL 4812443, at *4. This particularity means that the plaintiff must "set forth the who, what, when, where, and how of the alleged fraud." *Id.* at *3 (citing *U.S. ex rel. Stephenson v. Archer W. Contractors, L.L.C.*, 548 F. App'x 135, 139 (5th Cir. 2013)). Critical to meeting that burden, Relators must tie the submission of actual claims to the underlying conduct – here, alleged kickbacks – that render the claims "false." *See, e.g., U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) ("For a False Claims Act violation, [relator] must prove that at least one of [the] claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute").

The Fifth Circuit applies these high standards "with bite" and "without apology." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). A rigorous application of Rule 9(b) works to protect "a defendant's reputation" from the harm caused by "general [and] unsubstantiated fraud accusations," and to "prevent[] a claimant from searching for a valid particular claim after filing suit." *Am. Realty Trust, Inc. v. Hamilton Lane Advisors, Inc.*, 115 F. App'x 662, 667 (5th Cir. 2004).

Relators have alleged only general, nationwide schemes without any specifics regarding actual support services and how those services purportedly provide substantial, illegal value to physicians.[2] Moreover, Relators have failed to allege with particularity the submission of a single actual false claim, or to link any such false claims to the alleged kickback schemes. The lack of detail also results in a failure to plead the essential FCA elements with the required particularity. *See Paramedics Plus LLC*, 2017 WL 4812443, at *4. Each of these is an independent basis for dismissal under Rule 9.

A. The FAC Lacks Critical Details Regarding the Who, What, When, Where, and How of the Alleged Kickback Schemes.

Relators' failure specifically to describe the three alleged kickback schemes is hardly surprising given the superficiality of their "investigation." *See* FAC ¶ 87. The FAC provides no details concerning the knowledge of Relator Health Choice, and Relator Green never worked directly for any of the Defendants. The investigatory effort involved alleged interviews with a handful of former employees.[3] The FAC is lacking in details regarding the who, what, when, where, and how of Defendants' alleged kickback schemes and how those schemes are tied to the submission of any false claims.

1. Details Absent in Theory One (Nursing Services as Remuneration to Doctors)

The FAC describes only generally a nurse educator program in which Defendants employed trained nurses to assist patients who were taking the Medicines, characterizing the

[2] The fact that Relators identify the "assigned marketing region" of each Interviewee is insufficient to meet Rule 9(b)'s "where" requirement. *U.S. ex rel. Woodard v. DaVita, Inc.*, No. 1:05-CV-227, 2010 WL 11531271, at *6 n.2 (E.D. Tex. Dec. 21, 2010) (dismissing FCA claim where relator named several cities in which scheme occurred without naming "a single specific site . . .where the alleged fraud occurred").

[3] Of the seven confidential interviewees referenced in the FAC, according to Relators, four worked for Lash, two for Bayer, one for ABC, and none for Amgen nor Onyx. FAC ¶ 87. Relator Green worked for non-party Ashfield. *Id*. at ¶ 27.

"scheme" as free services to induce doctors to prescribe those products. *See, e.g.*, *id*. at ¶ 92. Relators do not provide dates, approximate or otherwise, during which the Adempas patient support program, AIM, was in operation. *Id*. at ¶ 95. They explain that one of the nurse educator programs, Beta Plus, "has been around for at least the last decade" before ending in 2015, and another, Nex Connect, "began at least as far back as 2009" and is still in operation. *Id*. This level of specificity as to timing is wholly inadequate under Rule 9. *See U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006) (alleging only the year in which fraud occurred was "insufficient to meet Rule 9(b)'s requirements to plead the 'when' with specificity").

The "who," "where," and "how" also are lacking in detail adequate to satisfy Rule 9. In FAC Paragraph 189, Relators list fifteen anonymous doctors ("Prescribers" 1-15) and the city and state in which they practiced, without providing details relevant to the alleged schemes.[4] For nine of these fifteen doctors, Relators *do not even allege* that the office or its patients utilized the nurse educator program. FAC ¶ 189 (alleging that Prescribers 1-3 and 8-10 "had patients educated by the nurse educators," but as to Prescribers 4-7 and 11-15, stating only that CI-2 or CI-5 "worked with" the Prescriber). It is wholly unclear how these doctors, their staffs, or their patients fit into the alleged schemes, or how any interactions could possibly have resulted in the submission of false claims. Moreover, even as to the six Prescribers whose patients allegedly received nurse education services, Relators offer no details regarding (1) who was involved (not a single staffer, patient, or anyone other than, by implication, the anonymous interviewee him- or herself); (2) where the nurse education occurred, given Relators' allegation that it was not generally at the doctors' offices, *see id*. at ¶ 96; or (3) when (beyond the general assertion that

[4] The Prescribers are located exclusively in Minnesota and New Jersey, FAC ¶ 189, despite Relators' allegation that the "programs were/are available to patients across the United States." *Id*. at ¶ 95.

"CI-2 educated Betaseron patients until 2015" and "CI-5 educated Nexavar patients in 2014 and 2015," *id*. at ¶ 189).[5] *See U.S. ex rel. Woodard v. DaVita, Inc*., No. 1:05-CV-227, 2011 WL 13196556, at *12 (E.D. Tex. May 9, 2011) ("Rule 9(b) simply does not allow [relator] to rest his pleading of a years-long scheme . . . on two allegations, each of which is itself significantly lacking in supporting facts.").

Furthermore, Relators offer no detail whatsoever to substantiate the bald and conclusory allegations that these support services provide "a tangible benefit," "freed up time to see other patients," and "increased profitability." FAC ¶¶ 106-07. Relators do not identify a single doctor who eliminated staff positions (or who such staff are) or otherwise received "substantial value" as a result of support services provided for the three Medicines at issue. This is not surprising because education services tailored to patients taking a specific medication would not allow doctors to eliminate entire administrative positions, significantly reduce costs, which are spread across many types of patients and treatments, or increase patient visits. Relators' failure to allege office-specific activities of the educators or value to doctors' offices is fatal to Theory One.

2. Details Absent in Theory Two (Remuneration to Nurses, or "White Coat Marketing")

The FAC's paragraphs devoted to Theory Two are similarly devoid of specifics. *See id*. at ¶¶ 108-45. Relators allege that "[s]ince at least 2006," defendants "have relied on nurse educators to help promote the Covered Products, obtain better access to Prescribers, and influence Prescribers to prescribe the Covered Products." *Id*. at ¶ 108. Relators claim that "training was a *vital* component" of the scheme, *id*. at ¶ 117, and that, "[o]nce trained, nurse

[5] For additional reasons discussed below, Paragraph 189 also lacks adequate details regarding the submission of actual reimbursement claims and the link between such claims and the three alleged kickback schemes. *See infra* Section II.B.

educators immediately began to gain access and infiltrate Prescriber offices and facilities," *id*. at ¶ 125. But Relators allege nothing about who trained the nurse educators; when such training took place; what facilities the nurse educators "infiltrate[d]"; where, other than "across the [entire] nation" these efforts occurred; or when, other than sometime over the past twelve years, any of this took place. *Id*. at ¶¶ 108, 125, 190.

Nor do Relators even generally allege any doctors or patients who may have been influenced by the so-called "white coat marketing" scheme such that a claim may have been caused to be submitted. In Paragraph 189, which purports to be a list of Prescribers "who received the free nurse education services or Support Services," there is no mention whatsoever of the educational services relevant to Theory Two. *See id*. at ¶ 189. The absence of these fundamental details is fatal to the Theory Two allegations under Rule 9.

3. Details Absent in Theory Three (Reimbursement Services as Remuneration to Doctors)

Relators generally allege that Defendants offered "free reimbursement support services" "to induce Prescribers to prescribe Betaseron and Nexavar to their patients." *Id*. at ¶¶ 146, 150. The services included "patient insurance benefit verification services, patient prior authorization services, and coverage appeals." *Id*. at ¶ 148. Relators recite publicly available information about the insurance industry and the kinds of administrative burdens it places on doctors' offices across the country, *see, e.g.*, *id*. at ¶¶ 151-55, 159-60, but provide virtually no detail about the fraudulent scheme Defendants allegedly carried out to capitalize on those burdens.

As with the other theories, Relators have provided inadequate detail regarding doctors who actually utilized reimbursement services or were influenced to prescribe medicines by the availability of those services. Only four of the fifteen Prescribers listed in Paragraph 189 are alleged to have "utilized the Support Services" at all, without any mention of when they sought

reimbursement, for which patients, or for what amounts. *Id*. at ¶ 189. As to those four Prescribers, the only individuals mentioned are CI-2 or CI-5 and the Prescribers, themselves. *Id*. But CI-2 and CI-5 *are nurse educators, not reimbursement support representatives*. *Id*. at ¶ 87. And by Relators' own account, "support staff," not prescribers, typically perform the administrative function to which the reimbursement services are relevant. *Id*. at ¶ 155. This means that the FAC, including newly added Paragraph 189, which includes only prescribers, does not identify *any* individuals who were involved in Theory Three.

Finally, despite repeatedly asserting that the reimbursement services provided "great value," "real value," and "tangible financial incentives" to prescribers, Relators do not allege anywhere in the FAC, much less with the required specificity, that a single physician eliminated administrative staff or somehow increased her patient load as a result of Defendants' reimbursement support services. As with their allegations regarding nursing support services, this is unsurprising because Relators' theory as to how reimbursement activities possibly could result in significant cost reductions or an increase in patient visits is implausible.

Courts in the Fifth Circuit routinely dismiss FCA complaints for failing to provide similar types and levels of detail.[6] The glaring dearth of detail across the alleged kickback schemes in this case likewise compels dismissal under Rule 9(b).

[6] *See U.S. ex rel. Doe v. Lincare Holdings, Inc.*, No. 5:15-CV-19-DCB-MTP, 2017 WL 752288, at *6 (S.D. Miss. Feb. 27, 2017) (dismissing FCA action as "lack[ing] the requisite indicia of the specific scheme to submit false claims" where the complaint "fails to identify any [] personnel who [participated in the scheme] or any billing personnel who submitted false claims as a result"); *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 771–72 (S.D. Tex. 2010) (dismissing FCA suit because the relator did not allege "the time or place of the allegedly false representations regarding [the drug], the nature or content of claims made which were allegedly fraudulent, or that doctors to whom Plaintiff promoted off-label use of [the drug] actually submitted false claims to the Government for off-label uses").

B. Relators Have Provided No Detail Regarding the Submission of False Claims, Much Less "Reliable Indicia" That False Claims Actually Were Submitted As a Result of the Alleged Schemes.

A separate basis for dismissal under Rule 9, Relators have failed to plead facts about the actual submission of any false claims as a result of the alleged kickback schemes. It is well established that the *sine qua non* of an FCA claim is the submission of an actual false claim for payment to the Government. *U. S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008). The FCA "statute attaches liability, not to the underlying fraudulent activity . . . but to the 'claim for payment.'" *U.S. ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 369 (5th Cir. 2011) (citation omitted). Even if Relators had sufficiently pled the existence of such "claims for payment," Relators must also allege with particularity that Defendants' challenged conduct *caused* them to be submitted. *Colquitt*, 858 F.3d at 372.

In the Fifth Circuit, if a relator cannot specify details of a particular false claim for payment, he must provide "reliable indicia" that lead to a "strong inference" that false claims were actually submitted. *U.S. ex. rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 895 (5th Cir. 2013). Conclusory allegations that false claims were submitted are "insufficient to serve as 'reliable indicia that leads to a strong inference that false claims were actually submitted.'" *U.S. ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 903 F. Supp. 2d 473, 487 (E.D. Tex. Feb. 8, 2011), *rev'd on other grounds*, 727 F.3d 343 (5th Cir. 2013); *see also Nunnally*, 519 F. App'x at 895 (finding "generalized allegations of false claims presented to the Government do not 'alleg[e] *particular* details of a scheme'" under Fifth Circuit's key *Grubbs* decision).

In *Grubbs*, the relator had first-hand knowledge of the fraudulent billing scheme. The court found that Grubbs' complaint satisfied Rule 9(b) where he named the doctors who allegedly perpetrated the scheme to bill for patient visits that never occurred; identified the date

that the doctors invited him to participate; identified the dates on which the nursing staff attempted to assist him in recording patient visits that did not occur; and provided dates on which the doctors billed Medicare and Medicaid for medical services that the doctors did not actually provide and the particular services they purported to provide. *Grubbs*, 565 F.3d at 191–92.[7]

Here, by contrast, Relators make extremely broad and conclusory allegations as to the submission of false claims. *See* FAC ¶¶ 184-86 (alleging that the fraudulent scheme encompasses "every Prescriber that, since at least 2006, received . . . 'free nurse' services," "a visit from a nurse educator," or "[reimbursement] Support Services" relating to the three products at issue); *id*. at ¶ 188 (alleging Defendants "have caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs . . . as a result of Defendants' illegal marketing and quid pro quo arrangements."). Relators' allegations are unsubstantiated, and as courts have held, it is not enough for Relator to "portray[] the scheme and then summarily conclude[]" that false claims were submitted as a result. *See U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 782 (S.D. Tex. 2010); *see also Forest Pharmaceuticals, Inc.*, 155 F. Supp. 3d at 893-94 (granting motion to dismiss FCA claims based on alleged AKS violations and a well-pled fraud scheme where relator could provide only "scant details" linking that detailed scheme to any government-reimbursed prescriptions allegedly resulting from that scheme). In fact, the FAC does not identify a single

[7] Courts routinely require a similar level of detail, even under a "reliable indicia" standard, for pleading the submission of false claims. *See, e.g.*, *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29–30 (1st Cir. 2009), *cert. denied*, No. 09-654 (2010) (finding allegations "a close call," but sufficient under a "more flexible" Rule 9(b) standard because the relator identified eight specific hospitals that submitted false claims along with "the dates and amounts of the false claims filed by these providers with the Medicare program") (citation omitted); *U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, No. EP-07-cv-247, 2008 WL 4277150, at *5 (W.D. Tex. Sept. 2, 2008) (allegations provided names of physicians perpetrating fraud, "the number of instances" of fraudulent services, "exact dates," the "medical histories" of relevant patients, "the number of claims submitted," "the number of payments fraudulently obtained," and "how and by whom false records were generated").

doctor, patient, or anyone else who submitted a false reimbursement claim, let alone the approximate date or amount of the claim. Courts routinely dismiss FCA complaints for lacking such details. *See Lam*, 481 F. Supp. 2d at 688 (dismissing complaint that did not "identify . . . specific physicians" who submitted false claims or "allege at least approximate dates of the alleged fraud") (citation omitted); *U.S. ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 883 (W.D. Tex. 2005) (same).

Despite Relators' attempt in FAC Paragraph 189 to provide information regarding a few Prescribers, an obvious flaw in their allegations remains that they do not tie any of the inadequately detailed support services to the actual submission of any reimbursement claim. For instance, regarding "Prescriber 1", who is representative[8] of the remaining six Prescribers who allegedly received some type of support services, Relators state:

> Prescriber 1, a doctor located in Golden Valley, Minnesota. Prescriber 1 was among the 1,000 highest prescribers of Betaseron to Medicare patients in 2014 and 2015. Prescriber 1 had patients educated by the nurse educators and utilized the Support Services provided by Defendants. CI-2 was first introduced to Prescriber 1 in 2007. CI-2 educated Betaseron patients until 2015, including patients of Prescriber 1.

FAC ¶ 189.

Relators assert that Prescriber 1 was at least the 1,000th highest prescriber of Betaseron for 2014-2015 (which could mean that she had only a few patients on the medicine). They then allege that Prescriber 1 "had patients" educated by CI-2 and "utilized the Support Services." *Id*. At no point do Relators "tie" these allegations "together into particularized charges about specific fraudulent claims for payment." *U.S. ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5,

[8] As explained above, *see supra* Section II.A.1, Relators have not alleged that Defendants provided any services whatsoever to nine of the fifteen doctors listed in Paragraph 189, instead opaquely stating that "CI-2 [or 5] worked with Prescriber[s]" 4, 5, 6, 11, 12, 13, 14, and 15. FAC ¶ 189. Prescriber 1 is "representative" of the remaining six doctors who Relators at least allege received (or that had patients receive) some type of support services.

15 (1st Cir. 2016). They do not allege any specific instance in which one of the Medicines was prescribed as a result of either the nurse educator programs or the reimbursement support services.[9] Nor do they then make the necessary connection that a claim was then submitted through Government healthcare programs. *See U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("[I]t would be speculation to infer that compensation for professional services legally rendered *actually caused* the physicians to prescribe [defendant's] drugs to Medicaid patients.") (emphasis added). Although Relators allege that Prescriber 1 was a Top 1000 Medicare prescriber, they do not allege that the patients with whom CI-2 worked were covered by Government reimbursement programs or privately insured patients. Relators apparently hope the court will just assume that the alleged patients were Government beneficiaries.[10]

The charts of publicly available information regarding Medicare and Medicaid reimbursements do nothing to remedy the disconnect between the alleged underlying conduct and any actual false claims for reimbursement. *See* FAC ¶¶ 192-204. At most, the charts generally show Medicare and Medicaid reimbursement for the Medicines in 2015 (the only year Medicare figures are included) and in some cases, from 2012 to 2014 (during which some Medicaid data is included). *See United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *24-25 (N.D. Tex. June 20, 2016), *reconsideration denied sub nom.*

[9] Contrary to Relators' liability theories, in fact, Relators' own allegations suggest the prescription of the Medicines was caused by factors other than any alleged remuneration. The confidential interviewees from Relator Health Choice's investigation admit that the Medicines are "beneficial" and the data "clearly show[s]" that the Covered Products are superior to competing drugs. *See* FAC ¶¶ 137, 143.

[10] There are no allegations under which the services allegedly provided to prescribers were conditioned on the prescribers prescribing Medicines to patients who would be reimbursed from the government. *See King*, 871 F.3d at 332 ("There was nothing illegal about paying physicians for their participation in these types of programs and there is no evidence that participation was conditioned upon prescribing [defendant's] drugs to Medicaid patients.").

U.S. ex rel. Wall v. Vista Hospice Care, Inc., No. 3:07-CV-0604-M, 2017 WL 5483747 (N.D. Tex. Nov. 14, 2017) ("The mere fact 93% of Defendants' patients are Medicare patients is not sufficient to show Defendants submitted claims that falsely certified compliance with the AKS. Courts regularly reject FCA claims which rely on probability arguments like Relator's."); *see also U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 58 (1st Cir. 2017) (holding that "aggregate [information] reflecting the amount of money expended by Medicaid" on off-label prescriptions was "insufficient"" because it did not show "an actual false claim made to the [G]overnment."). Nothing in the FAC indicates what portion, if any, of these claims were "false," nor have Relators bolstered these figures with "factual or statistical evidence to strengthen the inference of fraud beyond mere possibility."[11] *Nunnally*, 519 F. App'x at 893; *see also U.S. ex rel. Lawton v. Takeda Pharm. Co.*, 842 F.3d 125, 132 (1st Cir. 2016) (finding relator's allegation that "as much as" 30% of Actos annual sales were for off-label prescriptions, combined with total reimbursement figures for Actos prescriptions during a certain period, failed "to show that doctors, patients, or patients' private insurers did seek out federal reimbursement for off-label Actos prescriptions.") (internal citation omitted).

Relators' utter failure to connect the alleged support services and kickback schemes to the submission of any actual false claims for payment compels dismissal under Rule 9.

C. Relators Have Failed to Sufficiently Distinguish Between the Alleged Acts of Each Defendant.

The lack of particularity pled in the FAC is apparent from the lack of specific allegations as to each Defendant. "[A] complaint containing 'general allegations, which does not state with

[11] Notably, Minnesota, the only state with allegations about specific Prescribers of Betaseron, *see id.* ¶ 189, only had 70 Betaseron patients on Medicare in 2015, *see id.* ¶ 192. Similarly, New Jersey, the only state with allegations about specific Prescribers of Nexavar, *see id.* ¶ 190, had just 153 Nexavar patients on Medicare in 2015, *see id.* ¶ 189. These low figures belie Relators' insinuation (and bald assumption) that Medicare claims were submitted for the patients who benefitted from CI-2 and CI-5's services.

particularity what representations each defendant made' does not meet the Rule 9(b) particularity requirement." *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 546 (S.D. Tex. 2011), *order vacated in part on reconsideration on other grounds*, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) (citing *Unimobil 84, Inc. v. Spurney*, 797 F.2d 214, 217 (5th Cir. 1986)); *see also Grubbs*, 565 F.3d at 192 (evaluating sufficiency of allegations as to different defendants separately). "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1184 (9th Cir. 2016) (quoting *United States v. Corinthian Colls.*, 655 F.3d 984, 997-98 (9th Cir. 2011)) ("flaw" in plaintiff's allegations was "failure to allege particular details of the scheme as applied to" three of the defendants).

Relators have improperly "lumped" all Defendants together in several ways. For example, although Relators concede that Amgen and Oynx *only* co-marketed the drug Nexavar and that Amgen and Onyx had no involvement in the manufacture or marketing of Betaseron and Adempas, *see* FAC ¶ 2, Relators nevertheless discuss *all* Defendants, *all* the Medicines, and *all* the alleged schemes together without setting forth the details of Amgen/Oynx's own participation, if any, in the alleged activities. *See, e.g., id.* at ¶ 92 ("Bayer and Amgen offered free nurse education and patient management services to induce prescribers to recommend the Covered Products . . . ."); *id*. at ¶ 108 ("Bayer and Amgen have relied on nurse educators to help promote the Covered Products . . . and influence Prescribers to prescribe the Covered Products."); *id*. at ¶ 146 ("Bayer and Amgen, with the assistance of Lash, offered . . . free reimbursement support services for Prescribers who wrote prescriptions for Betaseron or

Nexavar."). Even allegations relating solely to Nexavar do not sufficiently plead the "who" of the alleged activity, as the drug is alleged to have been co-marketed by both Bayer and Amgen, making it impossible to determine which Defendant committed what alleged act. *See id*. at ¶ 2.

The sources through which Relators conducted their investigation further highlight the lack of information as to particular Defendants. *None* of the CIs were employed by Amgen or Onyx, and of the eight individuals interviewed, only two worked with Nexavar (CI-5, employed by Lash, and CI-6, employed by Bayer). *See id*. at ¶ 87. Similarly, none of the CIs purport to connect ABC or Lash with the drug Adempas, even though it is included within Relators' catch-all definition of "Covered Products." Because Relators improperly draw all Defendants together without providing the requisite level of detail regarding their "role . . . in the alleged fraudulent scheme," the claims should be dismissed. *United Healthcare Ins. Co.*, 848 F.3d at 1184.

III. The Conspiracy Claim (Count 3) Should Be Dismissed Because the FAC Fails to Allege the Essential Elements of a Conspiracy Claim.

FCA conspiracy requires "(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by the Government and (2) at least one act performed in furtherance of that agreement." *Grubbs*, 565 F.3d at 193 (quoting *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343 (5th Cir. 2008)). Moreover, Relators must show that conspirators had a "meeting of the minds . . . on the object or course of action," *U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 857 (S.D. Tex. 2003), *aff'd*, 384 F.3d 168 (5th Cir. 2004), as well as "a specific intent to defraud" the Government at the inception of the agreement, *Farmer*, 523 F.3d at 343. Relators must plead these elements with the particularity required by Rule 9(b). *Grubbs*, 565 F.3d at 193.

As an initial matter, Relators' conspiracy claim fails simply because they have not pled any underlying FCA violation, as explained above. *U.S. ex rel. Graves v. ITT Educ. Servs., Inc.*,

284 F. Supp. 2d 487, 509 (S.D. Tex. 2003), *aff'd*, 111 F. App'x 296 (5th Cir. 2004) (conspiracy claim failed as a matter of law because underlying FCA claims were dismissed under Rule 12(b)(6)).

In addition, Relators have not pled their conspiracy claim with the requisite particularity. Relators insist that "Bayer and Amgen conspired with Amerisource and Lash, physicians, and other health care professionals" to violate the FCA. FAC ¶ 218. Yet nowhere do Relators allege—let alone with particularity—that Bayer and Amgen had any unlawful agreement to conspire with each other, with Amerisource and Lash, or with other health care professionals to defraud the Government.[12] That alone is fatal. *U.S. ex rel. McLain v. Fluor Enters., Inc.*, No. CIV.A. 06-11229, 2013 WL 3899889, at *10 (E.D. La. July 29, 2013) (dismissal where complaint did not provide "any indication that any of the parties actually agreed to enter into the alleged conspiracy"). Indeed, this Court and others have found conspiracy claims with more specific allegations than exist in this case to be legally deficient. *See, e.g.*, *U.S. ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 208 (E.D. Tex. 1998) (dismissing conspiracy claims under Rule 9(b) despite allegations of "a pattern of . . . coordinated schemes," of misrepresentations through "buy/sell agreements between [defendants]," that defendants "knowingly employed these schemes in a calculated and concerted effort to cheat the United States," that they "entered into [agreements] with each other" to make misrepresentations, and that "[e]very defendant performed an overt act in furtherance of the conspiracy.").[13]

[12] *See* Theory One, *id.* at ¶¶ 92-107 (merely making two conclusory statements that "Bayer and Amgen provided these services through Amerisource and Lash nurses," *id.* at ¶ 92, and "with the assistance of Amerisource and Lash," *id.* at ¶ 107); Theory Two, *id.* at ¶¶ 108-45 (only vaguely alleging that Bayer and Amgen acted "with assistance from Amerisource, Lash, and Ashfield" *see, e.g., id.* at ¶ 108); Theory Three, *id.* at ¶¶ 146-73 (generally stating that Bayer and Amgen provided services "with the assistance of Lash," *see, e.g., id.* at ¶ 146).

[13] Even if the Amended Complaint could be construed as alleging a conspiracy between Amerisource and its subsidiary Lash, the claim would be barred for the additional reason that a corporation cannot conspire

IV. The State Law Counts (Counts 4-34) Should Be Dismissed For the Same Reasons as the FCA Claims and For Failure to Satisfy Rule 9(b)

State law analogues to the FCA create liability for false claims, often with language identical or very similar to the FCA. *See* FAC ¶ 40 ("Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS."). Absent allegations about how a state law differs from the FCA – which Relators have not pled here – courts interpret state false claims laws consistently with the FCA. *See, e.g. U.S. ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 537-38 (N.D. Tex. 2012), *aff'd* 858 F.3d 365 (5th Cir. 2017) (dismissing both FCA and state law claims with prejudice concurrently when requirements of FCA were not met and no difference in state law was shown). Just as they have failed to adequately allege a violation of the federal FCA, Relators have not adequately pled a violation of any of the state statutes, and their state law claims should be dismissed on that basis.

Like federal FCA claims, state law FCA claims are also subject to Rule 9(b). *See Williams v. WMX Technologies, Inc.*, 112 F.3d 175, 177 (5th Cir. 1997). To meet this heightened pleading standard, Relators must include state-specific allegations for each state law claim. *See U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. 2011) (dismissing certain state law claims under Rule 9(b) where relator "provide[d] no details of the alleged fraud" specific to those states). Here, Relators have pled no substantive allegations beyond those alleged in support of their federal claims, and therefore the state claims should be dismissed even if the federal claims are not. *See id*.[14]

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with its own subsidiary. *Reagan*, 274 F. Supp. 2d at 856 (citing *Deauville Corp. v. Federated Dept. Stores, Inc.*, 756 F.2d 1183, 1192 (5th Cir. 1985)) ("[I]t is a matter of law that a parent corporation cannot conspire with its own subsidiary.").

[14] Alternatively, should the Court dismiss Relators' federal FCA claims for any reason, it should decline to exercise supplemental jurisdiction over Relators' state law claims. *See United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 828 (E.D. Tex. 2008) (noting that "the 'general rule' in

V. A Substantial Portion of Relators' Pled Claims Are Time Barred.

The Relators' *qui tam* action is subject to the FCA's six-year statute of limitations. 31 U.S.C. § 3731(b)(1); *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 816 (E.D. Tex. 2008); *see also U.S. ex rel. Jackson v. Univ. of N. Tex.*, 673 F. App'x 384, 387 (5th Cir. 2016) (unpublished per curiam) ("In this circuit . . . *qui tam* FCA actions are governed by the limitations period found in § 3731(b)(1)."). The limitations period begins on the "the date on which the violation . . . is committed"—that is, the date on which "the defendant submitted a false claim for payment." *Graham Cnty Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 545 U.S. 409, 415-16 (2003). Because Relators filed this action on June 19, 2017, Dkt. 1, they are barred from claiming any FCA violation based on claims submitted before June 19, 2011. To the extent Relators seek recovery for claims submitted before that date, all such claims under Counts 1, 2, and 3 should be dismissed.

Relators' claims under various state laws—in Counts 4-34—similarly are subject to limitations periods and partially time-barred.[15]

VI. The FAC Improperly Added Relator Green.

Relators have violated the FCA's procedural rules by adding a new relator—Green—to

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the Fifth Circuit is to decline to exercise jurisdiction over pendent state law claims when all federal claims are eliminated from a case before trial").

[15] Eighteen of those are asserted under state laws containing substantially identical statutes of limitations, and also should be restricted to claims submitted on or after June 19, 2011. *See, e.g.*, (Count 5) Cal. Gov't Code § 12654(a); (Count 8) Del. Code Ann. tit. 6, § 1209(a); (Count 9) D.C. Code Ann. § 2-381.05(a); (Count 10) Fla. Stat. Ann. § 68.089(1); (Count 11) Ga. Code Ann. § 49-4-168.5; (Count 13) 740 Ill. Comp. Stat. Ann. 175/5; (Count 14) Ind. Code Ann. § 5-11-5.5-9(b); (Count 15) Iowa Code Ann. § 685.4(2); (Count 19) Mich. Comp. Laws Ann. § 400.614; (Count 20) Minn. Stat. Ann. § 15C.11(a); (Count 22) Nev. Rev. Stat. Ann. § 357.170(1); (Count 23) N.H. Rev. Stat. Ann. § 167:61-b(VII); (Count 24) N.J. Stat. Ann. § 2A:32C-11; (Count 27) N.C. Gen. Stat. Ann. § 1-615; (Count 28) Okla. Stat. Ann. tit. 63, § 5053.6(B); (Count 29) 9 R.I. Gen. Laws Ann. § 9-1.1-5(b); (Count 30) Tenn. Code Ann. § 71-5-184(b); (Count 31) Tex. Hum. Rem. Code § 36.104(b); (Count 32) Vt. Stat. Ann. tit. 32, § 639(a); *see United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 538 (S.D. Tex. 2011), *order vacated in part on reconsideration of other grounds*, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) (applying six-year limitations period to state-law claims with statutes "substantially similar to the federal FCA limitations clause"). Several state-law equivalents have even shorter limitations periods. *See* Ark. Code Ann. § 20-77-908 (Count 4) (five-year SOL); N.M. Stat. Ann. § 27-14-13(a) (Count 25).

this suit through the FAC. Regardless of how Relators frame this late addition, it runs headfirst into an insurmountable roadblock requiring Green's dismissal from this action: the FCA's first-to-file rule, which bars a litigant from joining an earlier-filed action and asserting claims based on the same facts. *See U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 378 (5th Cir. 2009) (holding that "a relator cannot avoid § 3730(b)(5)'s first-to-file bar by simply adding factual details . . . to the essential or material elements of a fraud claim against the same defendant described in a prior compliant.").

Green's addition violates the first-to-file rule. In the FAC, Green purports to join in all the allegations that Health Choice previously made in the original complaint. The FAC defines Health Choice *and* Green collectively as the "Relators," FAC at 1, and proceeds to make every allegation and substantive claim on behalf of both. Moreover, comparing the two Relators' allegations in the FAC against Health Choice's allegations in the original complaint shows that the FAC contains virtually verbatim recitations of the alleged "schemes" from the original complaint. *Compare* FAC ¶¶ 92-173, *with* Original Complaint ¶¶ 76-152. Of the 82 paragraphs containing these allegations in the FAC, 78 were already made in the original complaint.[16] Green therefore adopts Health Choice's earlier allegations as her own, and together, both Relators reiterate them in the FAC.

Section 3730(b)(5) makes clear that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." This first-to-file rule is a jurisdictional bar to claims that allege "the same material or essential elements of fraud described in a pending *qui tam* action[.]" *Allstate*, 560 F.3d at 378. Federal courts hold that this

[16] Relators made only inconsequential changes to a handful of the other 78, pre-existing paragraphs. *See, e.g.*, FAC ¶ 93 (adding single sentence of Green's salary with Ashfield); *id.* at ¶¶ 108, 110 (adding nonparty "Ashfield"); *id.* at ¶ 116 (changing "Relator" to "HCG"); *id.* at ¶ 167 (changing "the Covered Products" to "Betaseron or Nexavar").

rule is "exception-free" and prevents a relator from "consolidating his claim with an earlier action." *See U.S. ex rel. Denenea v. Allstate Ins. Co*., No. CIV.A. 07-2795, 2011 WL 231780, at *1 (E.D. La. Jan. 24, 2011); *U.S.. ex rel. Lujan v. Hughes Aircraft Co*., 243 F.3d 1181, 1187 (9th Cir. 2001) (stating "§ 3730(b)(5)'s plain language does not contain exceptions[, which] . . . conforms with the dual purposes of the 1986 [FCA] amendments: to promote incentives for whistle-blowing insiders and prevent opportunistic successive plaintiffs.").

Green attempts here what the FCA expressly prohibits: intervening in an earlier-filed action and asserting claims based on the same allegations that already were pled. Her claims would have been barred if she had sought to bring a new, separate lawsuit based on her allegations. She therefore should be dismissed from this action.

CONCLUSION

For the forgoing reasons, Defendants request that the Court dismiss with prejudice Relators' claims.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 21st day of February, 2018.

/s/ T. John Ward, Jr.